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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,782	03/11/2005	Eric Mabry	521-28-PCT-PA	9563
22145 7590 09/27/2007 KLEIN, O'NEILL & SINGH, LLP 43 CORPORATE PARK SUITE 204 IRVINE, CA 92606			EXAMINER RIVELL, JOHN A	
			ART UNIT 3753	PAPER NUMBER
			MAIL DATE 09/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/527,782

Applicant(s)

MABRY ET AL.

Examiner

John Rivell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/11/05 (application).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-20 and 24-29 is/are rejected.
- 7) ☒ Claim(s) 8-10, 21-23 and 30-32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 03112005, 09132007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claims 1-32 are pending. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11 and 14 are rejected under 35 U.S.C. §102 (b) as being anticipated by Hiejima (U. S. Pat. No. 5,925,023 cited by applicant).

The patent to Hiejima discloses, in figure 2 for example, a “device for selectively regulating the flow rate of a fluid, comprising: a housing (4, at lid 41 and body 42) including an inlet (1) and an outlet (2); a plurality of flow conduits (flow paths 31, 32, 33) fluidly connected between the inlet (1) and the outlet (2), the flow conduits (31, 32, 33) being of substantially equal inside diameters, each of the flow conduits having a length representative of a different pre-defined flow rate (and of selected different lengths); and a flow rate selection mechanism (at 51, 52, 52), operatively mounted in the housing, for selectively obstructing fluid flow through the flow conduits (31, 32, 33), thereby to provide a flow rate from the inlet (1) to the outlet (2) corresponding to the combined flow rates of the unobstructed flow conduits” as recited.

Regarding claim 11, Hiejima discloses an “infusion system for delivering selectable flow rates of a therapeutic liquid to a patient, comprising: a pressurized fluid

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reservoir (connected at inlet 1) containing a volume of the liquid and having an outlet; and a flow-regulating device (fig. 2 having) an inlet (1) fluidly coupled to the outlet of the reservoir and an outlet (2) coupled to an IV conduit (eventually connected to a patient); wherein the flow-regulating device comprises: a plurality of flow conduits (31, 32, 33) fluidly connected between the inlet (1) and the outlet (2), the flow conduits being of substantially equal inside diameters, each of the flow conduits having a length representative (e.g. of different length) of a different pre-defined flow rate; and a flow rate selection mechanism (a 51, 52, 53) for selectively obstructing fluid flow through the flow conduits, thereby to provide a flow rate from the inlet (1) to the outlet (2) corresponding to the combined flow rates of the unobstructed flow conduits" as recited.

Regarding claim 14, in Hiejima "a plurality of flow conduits (31, 32, 33 are) fluidly connecting the inlet (1) and the outlet (2) of the flow-regulating device, the conduits being of substantially equal internal diameter, each of the conduits having a particular (different) length that determines a pre-defined flow rate of the liquid through the device; and a flow rate selection mechanism (at 51, 52, 55) that is (selectively, fig. 5) actuable to selectively block liquid flow through (a) none of the flow conduits, and (b) one or more of the conduits" as selected, as recited.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-7, 15-20 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiejima in view of Hogner (U. S. Pat. No. 5,113,906).

The patent to Hiejima discloses all the claimed features including having "the flow rate selection mechanism (comprising) a flow-blocking element (521, 522, 523) operatively associated with each of the flow conduits (31, 32, 33), each flow-blocking element being selectively operable (based on the selected flow rate set as shown in fig. 5) to block fluid flow through its associated conduit".

The device of Hiejima does not include "an actuation mechanism operatively engageable with each of the flow-blocking elements and movable among a plurality of pre-defined positions in all but one of which it operatively engages one or more of the flow-blocking elements to block flow through the flow conduit associated with each of the operatively-engaged flow- blocking elements, and in one position of which it operatively engages none of the flow-blocking elements".

The patent to Hogner discloses that it is known in the art to employ a single actuator at handle 13, actuating several "cams" 11a, b, c, etc. simultaneously, each cam operating an intermediate "resilient element 14 which in turn is pressed against a collapsible tube 6-10 for the purpose of simultaneously actuating several "valves" as tube compressors, with a single actuator input.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ in Hiejima a single actuator, operating as many cams as there are collapsible tubes 31, 32, 33, by actuating an intermediate element

which in turn is pressed against the collapsible tube for the purpose of actuating all of the "valves", i.e. collapsible tubes, of Hiejima with a single actuator input as recognized by Hogner.

Regarding claim 3, in the device of the combination, "each of the flow conduits (31, 32, 33 of Hiejima) includes a resiliently compressible occlusion tube (61, 62, 63), and wherein each of the flow-blocking elements comprises a resilient element (such as at 14 of Hogner) that is movable into and out of a flow-blocking compression against its associated occlusion tube" as recited.

Regarding claim 4, in the device of the combination, "the actuation mechanism comprises a plurality of cam elements (11a, b, c, of Hogner), each of which is positioned operatively to move one of the resilient elements (14 of Hogner) into a flow-blocking compression against its associated occlusion tube (61, 62, 63 of Hiejima)" as recited.

Regarding claim 5, in the device of the combination, "each of the resilient elements (14 of Hogner) comprises a resilient cam follower finger located so as to be operatively urged into a compressive engagement with one of the occlusion tubes (61, 62, 63 of Hiejima) when the cam follower finger (14 of Hogner) is engaged by a cam element (11a, b, c of Hogner)" as recited.

Regarding claim 6, in the device of the combination, "a cam rotor (such as at handle 13 and shaft 4 of Hogner is) rotatably mounted in the housing (of Hiejima) and having the cam elements (11a, b, c of Hogner are) disposed thereon in positions in which each of the cam elements (11a, b, c) may operatively engage an associated cam follower finger (14 of Hogner) as the cam rotor is rotated" as recited.

Regarding claim 7, in the device of the combination, "the cam rotor (shaft 4 of Hogner) is rotatable among a plurality of rotary positions, each of which is associated with a predefined fluid flow rate" through conduits 31, 32, 33 of Hiejima as recited.

Regarding claim 15, in the device of the combination, "the flow rate selection mechanism comprises: a flow-blocking element (521, 522, 523 of Hiejima) operatively associated with each of the flow conduits (31, 32, 33 of Hiejima); and an actuation mechanism (e.g. handle 13 of Hogner) selectively actuates the flow blocking elements to block flow through the flow conduit associated with each actuated flow blocking element" as recited.

Regarding claim 16, in the device of the combination, "each of the flow conduits (31, 32, 33 of Hiejima) includes a resiliently compressible occlusion tube (61, 62, 63), and wherein each of the flow blocking elements includes a resilient element (such as at 14 of Hogner) that is movable by the actuation mechanism (cams 11a, b, c of Hogner) into a flow-blocking compression against its associated occlusion tube" as recited.

Regarding claim 17, in the device of the combination, "the actuation mechanism comprises a plurality of cam elements (11a, b, c of Hogner), each of which is positioned operatively to move one of the resilient elements (14 of Hogner) into a flow-blocking compression against its associated occlusion tube (61, 62, 63 of Hiejima)" as recited.

Regarding claim 18, in the device of the combination, "each of the resilient elements (14 of Hogner) comprises a resilient cam follower finger located so as to be operatively urged into a compressive engagement with one of the occlusion tubes (such as at 6-10 of Hogner; 61, 62, 63 of Hiejima) when the cam follower finger (the tip of element 14) is engaged by a cam element" as recited.

Regarding claim 19, in the device of the combination, "the flow regulating device further comprises a housing (4 of Hiejima) containing the flow conduits (31, 32, 33) and the cam follower fingers (14 of Hogner), the housing having one end including the device inlet (1) and another end including the device outlet (2); and wherein the actuation mechanism further comprises a cam rotor (shaft 14 of Hogner) rotatably

mounted in the housing and having the cam elements (11a, b, c) disposed thereon in positions in which each of the cam elements (11a, b, c) may operatively engage an associated cam follower finger (14 of Hogner) as the cam rotor (14) is rotated" as recited.

Regarding claim 20 in the device of the combination, "the cam rotor (14 of Hogner) is rotatable among a plurality of rotary positions, each of which is associated with a predefined fluid flow rate" as recited.

Regarding claim 24, in the device of the combination discloses a "device for regulating the flow of a liquid from a pressurized source, comprising: a housing (4 of Hiejima) having an inlet (1) and an outlet (2); at least first (at 31), second (at 32), and third (at 33) flow conduits in the housing fluidly connecting the inlet (1) and the outlet (2), each of the flow conduits (31, 32 and 33) comprising a flow control tube (31, 32, 33) and a resiliently compressive occlusion tube (61, 62, 63), wherein the flow control tubes are of substantially equal internal diameter, the first flow control tube (at 31) having a first length associated with a first pre-defined flow rate, the second flow control tube (at 32) having a second length associated with a second pre-defined flow rate, and the third flow control tube (at 33) having a third length associated with a third pre-defined flow rate; a resilient flow-blocking element (14 of Hogner) operatively associated with each of the occlusion tubes (61, 62, 63) and movable into a flow-blocking compression against its associated occlusion tube (61, 62, 63); and an actuation mechanism (handle 13 and shaft 4 of Hogner) in the housing (4 of Hiejima) that is operable (a) to selectively engage and move one or more of the flow-blocking elements (14 of Hogner) into the flow-blocking compression against its associated occlusion tube (61, 62, 63 of Hiejima), and (b) to selectively be disengaged from any of the flow-blocking elements" as recited.



Regarding claim 25, in the device of the combination, "the actuation mechanism is operatively engageable with each of the flow-blocking elements (14 of Hogner) and is movable among a plurality of pre-defined positions in all but one of which it operatively engages one or more of the flow-blocking elements (14 of Hogner) to block flow through the occlusion tube (61, 62, 63 of Hiejima) associated with each of the operatively-engaged flow-blocking elements (14 of Hogner), and in one position of which it operatively engages none of the flow-blocking elements" as recited.

Regarding claim 26, in the device of the combination, "the actuation mechanism comprises a plurality of cam elements (11a, b, c of Hogner), each of which is positioned operatively to move one of the resilient elements (14 of Hogner) into a flow-blocking compression against its associated occlusion tube (61, 62, 63 of Hiejima)" as recited.

Regarding claim 27, in the device of the combination, "each of the resilient elements comprises a resilient cam follower finger (14 of Hogner) located so as to be operatively urged into a compressive engagement with one of the occlusion tubes (6-10 of Hogner: 61, 62, 63 of Hiejima) when the cam follower finger (14) is engaged by a cam element (11a, b, c of Hogner)" as recited.

Regarding claim 28, in the device of the combination, "a cam rotor (shaft 4 of Hogner) rotatably mounted in the housing (4 of Hiejima) and having the cam elements (11a, b, c of Hogner) disposed thereon in positions in which each of the cam elements (11a, b, c of Hogner) may operatively engage an associated cam follower finger (14 of Hogner) as the cam rotor (shaft 4 of Hogner) is rotated" as recited.

Regarding claim 29, in the device of the combination, "the cam rotor (shaft 4 of Hogner) is rotatable among a plurality of rotary positions, each of which is associated with a predefined fluid flow rate" as recited.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiejima in view of Gonnelli et al. (U. S. Pat. No. 6,939,324).

The patent to Hiejima discloses all the claimed features with the exception of having "a fill valve fluidly coupled between the outlet of the reservoir and the inlet of the flow-regulating device".

The patent to Gonnelli et al. discloses, in figure 18 for example, that it is known in the art to employ a "fill valve" at re-fill valve 324 upstream of the restriction device 322, in the infusion line set for the purpose of allowing the fluid circuit to be "refilled" with fluid.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ in Hiejima a "re-fill valve" located in the fluid circuit upstream of the restriction device at 4 and in the inlet circuit 91 for the purpose of permitting refilling of the supply reservoir without disconnecting the fluid circuit as recognized by Gonnelli et al.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiejima in view of the prior art as disclosed at para [0021] of the instant specification.

The patent to Hiejima discloses all the claimed features with the exception of having "the (supply) reservoir... pressurized by a pump applying a controllable pressure to the reservoir".

The prior art as disclosed at para [0021] of the instant specification discloses that it is known in the art to employ a pressurized, by a not shown pump, volume reservoir used as a supply reservoir of fluid to be infused into a patient. Such a pressurized reservoir clearly provides for more uniform control of a specific flow rate through the restriction device as opposed to a gravity flow system normally used, which would lose pressure as fluid is dispensed since the level of fluid drops in the reservoir.

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It would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ in Hiejima a pressurized reservoir of fluid, pressurized by a pump, supplying fluid to the restriction device 4 for the purpose of providing a more uniform control of desired flow rate through the restriction device 4 of Hiejima as recognized by the prior art disclosed at para [0021] of the instant specification.


Claims 8-10, 21-23 and 30-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Rivell whose telephone number is (571) 272-4918. The examiner can normally be reached on Mon.-Fri. from 6:30am-3:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Huson can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**John Rivell**  
**Primary Examiner**  
**Art Unit 3753**

j.r.